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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,809	04/26/2002	Ronit Eisenberg	24025-501	1519

7590 03/17/2004

EXAMINER
NOLAN, PATRICK J

ART UNIT	PAPER NUMBER
1644	

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DATE MAILED: 03/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,809	EISENBERG ET AL.	
	Examiner	Art Unit	
	Patrick J. Nolan	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-47 and 50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-4,and 47* is/are rejected.

7)☒ Claim(s) *44-46 and 50* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. This application is a 35 USC 371 of PCT/IL00/00346.

2. Claims 30-47and 50 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 30-43 stand rejected under 35 U.S.C. § 103 as being unpatentable over Kuby et al., (U), in view of Aridor et al. (V), and U.S. Patent 5,807,746 (A), all of record, for reasons set forth in the Paper mailed 8-11-2003.

Applicant's arguments filed 2-11-04 have been fully considered but are not found persuasive.

Applicant argues the Examiner is improperly using hindsight reconstruction to arrive at Applicant's claimed invention and that there was no proper motivation to arrive at Applicant's invention.

However, one of skill in the art at the time of Applicant's invention knew the following facts, that it was common in the art to treat in vivo allergies by administering compounds which inhibited mast cell degranulation, as taught by Kuby et al.

It was also known prior to Applicant's claimed invention that Arridor et al., taught a peptide that was successful in inhibiting mast cell degranulation, but was only able to do so ex vivo since the mast cells needed to be permeabilized to allow access to the inside of the mast cell for the inhibitory peptide.

It was also known prior to Applicant's invention that cell importation peptides could be used to import ANY biologically active peptide to the inside of the cell, as taught by the '746 patent.

So one of skill in the art would have been motivated to inhibit mast cell degranulation to treat allergies by combining the peptide of Aridor with the peptide of the '746 patent, since the peptide of the '746 cures the deficiencies of the Aridor et al., peptide for in vivo allergy treatment.

Applicant argues there was no expectation of success since the '746 patent doesn't importation of their peptide into mast cells.

However, the '746 patent teaches the importation of any biological peptide into any cell. It does not recognize that their invention would not work on mast cells. Furthermore, Applicant has not provided any evidence that mast cells have cell membrane structures that are different from normal cell membranes in such a way that one of skill in the art would not expect the cell importation peptide of the '746 peptide to import a biologically active to the inside of mast cells.

Lastly, Applicant argues that they have unexpected results, since they submit one of skill in the art would not have expected the in vivo importation of an anti-allergic agent into a mast cell in a subject to treat an allergic condition, since mast cells are unique.

Attorney's arguments cannot replace evidence where evidence is required, MPEP 2145. Applicant has provided no evidence that mast cells are unique in the fact that they would not incorporate and retain an anti-allergic agent instead of releasing them following allergen stimulation in a subject. They have provided no evidence with regards to in vivo versus in vitro functional differences of mast cells. Lastly, the scope of Applicant's claimed invention does not

correspond to "unexpected" results potentially demonstrated in the specification for select peptides.

4. Claims 30, 31 and 47 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Kuby et al., in view of Aridor et al., and US Patent 5,807,746 as applied to claims 30 and 31 above, and further in view of US Patent 6,103,692, for reasons set forth in the Paper mailed 8-11-2003.

Applicant argues that the the '692 patent does not teach in vivo treatment of allergies and therefore can not make obvious the claimed invention. See the examiner's response supra.

5. Claims 44-46 and 50 are free of the prior art as of the last search.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is 571-272-0847.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-272-0841.

Patrick J. Nolan, Ph.D.
Primary Examiner, Group 1640
March 15, 2004